UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/956,518	10/23/1997	SHERRY LEONARD	UTC-03042	8812

23535 7590 02/11/2003

MEDLEN & CARROLL, LLP
101 HOWARD STREET
SUITE 350
SAN FRANCISCO, CA 94105

EXAMINER	
HAYES, ROBERT CLINTON	
ART UNIT	**PAPER NUMBER**
1647	13

DATE MAILED: 02/11/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 08/956,518	Applicant(s) Leonard Et AL
	Examiner Robert C. Hayes	Group Art Unit 1645

☒ Responsive to communication(s) filed on *Jul 19, 1999*.

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire *3* month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) *1 and 3-8* is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) *1 and 3-8* is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐approved ☐disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

DETAILED ACTION

Election/Restriction

1. Applicant's election without traverse of Group I in Paper No. 12 is acknowledged.

Claims 2, 9-25 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b) as being drawn to a non-elected inventions. Election was made **without** traverse in Paper No. 12.

Information Disclosure Statement

2. The information disclosure statement filed 4/2/99 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each U.S. and foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. Note that Applicants are encouraged to use a PTO 1449.

Claim Rejections - 35 U.S.C. § 101

3. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter or any new and useful improvement thereof, may obtain a patent therefore, subject to the conditions and requirements of this title.

Claims 6-8 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. For example, the current recitation of "A first polynucleotide sequence... comprising..." encompasses all naturally occurring DNAs; thereby, not involving the hand of man to isolate or purify the DNA. Additionally, claims 6-7 encompass human hosts, in that no isolated host cell is claimed.

Claim Rejections - 35 USC § 112

4. Claims 3-4 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant specification discloses the DNA sequence for the human alpha-7 nicotinic receptor (e.g., Figs. 9-10), as well as some nucleotide sequences that encompass part of the promoter sequences for this gene (e.g., Fig. 4). However, no written description of the complete human alpha-7 nicotinic receptor nucleic acid sequence is disclosed (e.g., as it relates to any additional 5' or 3' flanking sequences); nor could one skilled in the art visualize any other human alpha-7 nicotinic receptor "intervening" or additional "5' or 3' flanking regions" besides those described within the instant specification (i.e., as it rtelates to claims 3-4). Without an adequate written description of any other enhancers, intervening regions, or other regulatory elements of the human alpha-7 nicotinic receptor gene, one skilled in the art could not visualize what constitutes "5' and 3' flanking regions", or different "intervening regions".

5. Claims 1 & 3-8 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the specific disclosed nucleotide sequences of SEQ ID NOs: 102 & 103 encoding the alpha-7 nicotinic receptor gene product, as well as the specific promoter nucleotides sequences "consisting of" SEQ ID Nos: 94 and 101, does not reasonably

provide enablement for any "portions" of nucleic acid molecule not encoding a functional alpha-7 nicotinic receptor protein, or nonfunctional promoters, or fragments of exon/intron boundaries with no function. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The name "nucleotide sequence encoding at least a portion of the human alpha-7 nicotinic receptor" does not sufficiently characterize and enable the polynucleotides that are encompassed by the claims, because the inclusion of "portions" thereof or incomplete sequences of an encoded alpha-7 nicotinic receptor sets forth little structural and little functional characteristics. In contrast, the specification does not teach which particular amino acids are critical for any alpha-7 nicotinic receptor protein's function that are encoded by these polynucleotides, or a single altered promoter sequence; nor how to distinguish any "portion" "comprising at least fifteen nucleotides" or "hybridization" product thereof from any different nucleic acid molecule that possesses none of the desired functions of the instant invention. It should be noted that a nucleic acid sequence that merely hybridizes to "at least 15 nucleotides' of a putative alpha-7 nicotinic receptor nucleic acid sequence does not necessarily possess the desired properties of a human alpha-7 nicotinic receptor molecule, without further structural and functional characterization to distinguish hybridization products with alpha-7 nicotinic receptor activity from any different molecule, or "portion" thereof, without alpha-7 nicotinic receptor activity (i.e., as it relates especially to claim 8). The skilled artisan would reasonably expect that any such random mutations or truncations to a

nucleic acid normally encoding an alpha-7 nicotinic receptor-related molecule would result in a polynucleotide encoding an inactive protein. For example, Rudinger states on page 3 that "it is impossible to attach a unique significance to any residue in a sequence. A given amino acid will not by any means have the same significance in different peptide sequences, or even in different positions of the same sequence". Rudinger further states on page 6 that "the significance of particular amino acid sequences for different aspects of biological activity cannot be predicted *a priori* but must be determined from case to case by painstaking experimental study". Therefore, the lack of guidance provided in the specification, as to what minimal structural requirements are necessary for a nucleic acid to encode a functional alpha-7 nicotinic receptor molecule would prevent the skilled artisan from determining whether any random mutations/truncations to the disclosed human alpha-7 nicotinic receptor DNA molecule could be made that retains the desired function of the instant invention, because any such polynucleotide would be expected by to encode proteins that have adversely altered their biologically active 3-dimensional conformation, even though such molecules may be still hybridizable under stringent conditions, without undue experimentation to determine otherwise.

Second, it is unknown "how to use" "portions thereof" because fragments encompass molecules with a lower limit of encoding a single amino acid residue that structurally does not distinguish the nucleic acids of the instant invention from any different nucleic acid protion. Nor would any nucleotide sequence encoding at least a portion of... that merely hybridizes to a human DNA sequence (i.e., as it relates to claim 8), be reasonably expected by one skilled in the art to

art to encode any functional or distinguishable protein product, because the specification fails to disclose those critical nucleotide or amino acid residues necessary for defining a functional "portion" thereof; thereby, requiring undue experimentation to discover how to make and use such, because the claims recite no assayable function for knowing how to use such molecules.

6. Claim 8 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In particular, the recitation "hybridizes under *stringent* conditions" is indefinite because it is unclear what metes and bounds are envisioned that defines whether low, medium, or high stringency conditions are envisioned.

Claim Rejections - 35 U.S.C. § 102

7. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

Claim 8 is rejected under 35 U.S.C. 102(e) as being anticipated by Elliott et al. (US Patent 5,837,489).

Elliott et al. teach nucleotide sequences from the human α-7 nicotinic acetylcholine receptor (i.e., SEQ ID NO:7; cols. 29 & 45-48) that are 100% identical to residue #s 321-447 of SEQ ID NO:94, residue #s 9-93 of SEQ ID NO:99, residue #s 8-37 of SEQ ID NO:100, residue #s 321-392 of SEQ ID NO:101, residue #s 423-529 of SEQ ID NO:102 and residue #s 423-529 of SEQ ID NO:103; thereby, anticipating the current limitations of being "at least 15 nucleotides which [inherently] hybridizes under stringent conditions to at least a portion of..." SEQ ID Nos: 84-103".

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to examiner Robert Hayes whose telephone number is (703) 305-3132. The examiner can normally be reached on Monday through Friday from 8:30 AM to 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. The fax phone number for this Group is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Robert C. Hayes, Ph.D.
August 5, 1999